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Atty. Docket No. 0501-UTL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. Serial No.: 10/559,595
Inventors: John ONG, et al
Filed: November 30, 2005
Title: NOVEL METHODS AND COMPOSITIONS FOR ENHANCED TRANSMUCOSAL DELIVERY OF PEPTIDES AND PROTEINS

Confirmation No.: Not Yet Assigned

TC/A.U.: Not Yet Assigned
Examiner: Not Yet Assigned

FACSIMILE TRANSMITTAL COVER SHEET

Certificate of Transmission Under 37 C.F.R. 1.8

I hereby certify that the following listed correspondence in the above-referenced application is being transmitted by facsimile to the Commissioner for Patents, Alexandria, VA to telephone number (571) 273-8300 on this 2nd day of August, 2006.

Susan A. Mogavero

Document(s)	No. of Pages
Request for corrected filing receipt	1
Filing Receipt	1
Corrected Filing Receipt	1
Transmittal Sheet as filed	3
Claims as filed	4

Total number of pages transmitted (including this page): 11

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Patent
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CORRETED FILING RECEIPT

Sir:

Applicant respectfully requests that the Filing Receipt for the above referenced patent application be corrected as follows:

Total Claims: 27

Independent Claims: 3

A copy of the original Filing Receipt and Filing Receipt with corrections indicated is attached hereto. In addition, please find a copy of the Transmittal Letter with the correct fee calculation to the US DO/EO/US concerning a submission under 35 U.S.C. 371 along with Claims 1-27 as filed.

No fees are believed due for this request for correction to filing receipt. However, if a fee is due, the Commissioner is authorized to charge any fees associated with the present filing to Deposit Account No. 01-0535.

Please call the undersigned at the number listed below if there are any questions concerning this submission.

Respectfully submitted,

Dated: 2 Aug 2006

By: _____
Susan J. Myers Fitch, Ph.D.
Reg. No. 55,477

AMYLIN PHARMACEUTICALS, INC.
9373 Towne Centre Drive
San Diego, CA 92121
Phone 858.309-7695
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18528.912

0501-UTL DT SMF

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY.DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/559,595	11/30/2005	1654	3100	0501-UTL-0	2	50	8

CONFIRMATION NO. 2750

44638
ARNOLD & PORTER LLP (18528)
555 TWELFTH ST, NW
WASHINGTON, DC 20004

ARNOLD & PORTER LLP
MAY - 2 2006
DOCKET

FILING RECEIPT

"OC000000018619208"

Date Mailed: 04/27/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Amylin Docketing
noted
☐ Previously Docketed NH

Applicant(s)

John Ong, San Marcos, CA;
Robert Jennings, San Diego, CA;
Gregg Stetsko, San Diego, CA;

Assignment For Published Patent Application

Amylin Pharmaceuticals, Inc., San Diego, CA

Power of Attorney: The patent practitioners associated with Customer Number 44638.

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/US04/17456 06/28/2004
which claims benefit of 60/474,233 05/30/2003

Foreign Applications

If Required, Foreign Filing License Granted: 04/25/2006

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is US10/559,595

Projected Publication Date: 08/03/2006

Non-Publication Request: No

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MAY 03 2006
AMYLIN PHARMACEUTICALS, INC.
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Due Date N/A
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UNITED STATES PATENT AND TRADEMARK OFFICE

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10/559,595	11/30/2005	1654	3100	0501-UTL-0	2	50 27	8 3

CONFIRMATION NO. 2760

44638
ARNOLD & PORTER LLP (18528)
555 TWELFTH ST, NW
WASHINGTON, DC 20004

ARNOLD & PORTER
MAY - 2 2006
DOCKET

FILING RECEIPT
[redacted]
"OC000000018519208"

Date Mailed: 04/27/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

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AMYLIN PHARMACEUTICALS, INC.
LEGAL DEPARTMENT

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PTO-1390 (Rev. 07-2005)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	
0501-UTL-0	
U.S. APPLICATION NO. (If known, see 37 CFR 1.5)	
INTERNATIONAL APPLICATION NO. PCT/US2004/017456	INTERNATIONAL FILING DATE May 28, 2004
PRIORITY DATE CLAIMED May 30, 2003	

TITLE OF INVENTION
Novel Methods and Compositions for Enhanced Transmucosal Delivery of Peptides and Proteins

APPLICANT(S) FOR DO/EO/US
John Ong, Gregg Stetsko, Robert Jennings

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☑ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☑ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☑ The US has been elected (Article 31).
5. ☑ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☐ is attached hereto (required only if not communicated by the International Bureau).
   b. ☐ has been communicated by the International Bureau.
   c. ☑ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☐ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☑ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☑ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☑ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☑ A preliminary amendment.
14. ☑ An Application Data Sheet under 37 CFR 1.76.
15. ☑ A substitute specification.
16. ☑ A power of attorney and/or change of address letter.
17. ☑ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the International application under 35 U.S.C. 154(d)(4).

PTO-1390 (Rev. 07-2005)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
	PCT/US2004/017456	0501-UTL-0

20. Other items or information: Substitute Specification - Marked-Up Version
Sequence Listing on Compact Disk (2 copies)
Compact Disk Transmittal Letter
Statement Under 37 C.F.R. 1.821(f)
Return Post Card

The following fees have been submitted	CALCULATIONS	PTO USE ONLY
21. ☑ Basic national fee (37 CFR 1.492(a)) $300	$ 300	
22. ☑ Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... $0 All other situations $200	$ 200	
23. ☑ Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... $0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority ..... $100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB ..... $400 All other situations $500	$ 100	
TOTAL OF 21, 22 and 23 =		
☐ Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(i)). The fee is $250 for each additional 50 sheets of paper or fraction thereof.		

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE	
62 - 100 =	0 /50 =		x $250	$ 0

Surcharge of $130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				$	
CLAIMS	NUMBER FILED		NUMBER EXTRA	RATE	
Total claims	27	- 20 =	7	x $ 50	$ 360
Independent claims	3	- 3 =	0	x $200	$ 0
MULTIPLE DEPENDENT CLAIM(S) (if applicable)				+ $360	$ 0
			TOTAL OF ABOVE CALCULATIONS =		$ 950
☐ Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.					
			SUBTOTAL =		$ 950
Processing fee of $130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				+	$
			TOTAL NATIONAL FEE =		$ 950
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property				+	$
			TOTAL FEES ENCLOSED =		$ 950
				Amount to be refunded:	$
				Amount to be charged	$

PTO-1390 (Rev. 07-2006)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

a. ☐ A check in the amount of $ _____ to cover the above fees is enclosed.

b. ☑ Please charge my Deposit Account No. 010535 in the amount of $ 950.00 to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☑ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 010535. A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

the address associated with Customer Number 44638

James E. Butler

SIGNATURE

James E. Butler, Ph.D.

NAME

40931

REGISTRATION NUMBER

What is claimed is:

1. A pharmaceutical composition for transmucosal administration of an exendin or exendin analog, comprising an exendin or an exendin analog, a cationic polyamino acid, and a buffer; wherein at the pH of the composition the buffer does not cause precipitation of the cationic polyamino acid and has a mono-anionic or neutral net charge; and wherein the transmucosal absorption of the exendin or exendin analog is increased relative to the absorption of the exendin or exendin analog in the absence of the polyamino acid.

2. The composition of claim 1, wherein the pH of the composition is between about pH 4.0 and about pH 6.0.

3. The composition of claim 1, wherein the pH of the composition is between about pH 4.0 and pH 5.0.

4. The composition of claim 1, wherein the buffer is selected from the group consisting of acetic acid, ε-aminocaproic acid or glutamic acid.

5. The composition of claim 1, wherein the buffer comprises glutamic acid.

6. The composition of claim 1, further comprising a tonicifying agent, a viscosity-increasing agent, a bioadhesive agent, a preservative, or any combination thereof.

7. The composition of claim 1, wherein the cationic polyamino acid comprises poly-histidine, poly-arginine, poly-lysine, or any combination thereof.

8. The composition of claim 7, wherein the cationic polyamino acid has an average molecule weight of between about 10 kDa and about 200 kDa.

9. The composition of claim 1, wherein the exendin or exendin analog is selected from at least one of the group consisting of exendin-3, exendin-4, exendin-4 acid,

exendin-4 (1-30), exendin-4 (1-30) amide, exendin-4 (1-28), exendin-4 (1-28) amide, ^{14}Leu, ^{25}Phe exendin-4 amide, and ^{14}Leu, ^{25}Phe exendin-4 (1-28) amide.

10. The composition of claim 1, wherein theexendin or exendin analog comprises exendin-4.

11. The composition of claim 1, wherein the exendin or exendin analog comprises exendin-3.

12. The composition of claim 1, wherein the exendin or exendin analog comprises at least one exendin selected from the group consisting of SEQ ID NOs: 9-39, 187 and 188.

13. The composition of claim 1, wherein the exendin or exendin analog comprises at least one exendin or exendin analog selected from the group consisting of SEQ ID NOs: 6-8 and 40-186.

14. The composition of claim 1, wherein the exendin or exendin analog comprises an amino acid sequence according to SEQ ID NO. 3.

15. The composition of claim 1, wherein the exendin or exendin analog comprises an amino acid sequence according to SEQ ID NO. 4.

16. The composition of claim 1, wherein the exendin or exendin analog comprises an amino acid sequence according to SEQ ID NO. 5.

17. The composition of claim 6, wherein the tonicifying agent is selected from the group consisting of sodium chloride, mannitol, sucrose, glucose and any combination thereof.

18. The composition of claim 6, wherein the viscosity-increasing agent is selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose, methylcellulose of average molecular weight between about 10 and about 1,500 kDa, starch, gums, and any combination thereof.

19. The composition of claim 6, wherein the bioadhesive agent is selected from the group consisting of carbomer, polycarbophil and any combination thereof.

20. The composition of claim 6, wherein the preservative is selected from the group consisting of phenylethyl alcohol, methylparaben, ethylparaben, propylparaben, butylparaben, chlorbutanol, benzoic acid, sorbic acid, phenol, m-cresol, alcohol, and any combination thereof.

21. The composition of claim 1, wherein the absorption is increased at least 2 fold.

22. The composition of claim 1, wherein the absorption is increased at least 5 fold.

23. The composition of claim 1, wherein the absorption is increased at least 10 fold.

24. A pharmaceutical composition for transmucosal administration of an exendin or an exendin analog comprising about 0.10% to about 5.0% (w/v) of an exendin or an exendin analog; about 0.01% to about 1.0% (w/v) of a cationic polyamino acid having a molecular weight between about 10 kDa and about 200 kDa; about 0.01% to about 10.0% (w/v) of a buffer, wherein at a pH of between about 4.0 and 5.0, the buffer does not cause precipitation of the cationic polyamino acid and the buffer has a mono-anionic or neutral net charge; and wherein the transmucosal adsorption of the exendin or exendin analog is increased relative to the adsorption of the exendin or exendin analog in the absence of the cationic polyamino acid.

25. The composition of claim 24, wherein the exendin or exendin analog comprises exendin-4.

26. A method for transmucosal administration of an exendin or an exendin analog comprising contacting a mucosal surface with a composition comprising an exendin or an exendin analog, a cationic polyamino acid, and a buffer for a time sufficient for a therapeutically effective amount of said exendin or exendin analog to pass through the mucosal surface; wherein at the pH of the composition, the buffer does not cause precipitation of the cationic polyamino acid and the buffer has a mono-anionic or neutral net charge; and wherein the transmucosal adsorption of the exendin or exendin analog is increased relative to the absorption of the exendin or exendin analog in the absence of the cationic polyamino acid.

27. The method of claim 26, wherein the exendin or exendin analog comprises exendin-4.